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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	#19

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

#19
8-21-03

Office Action Summary	Application No.	Applicant(s)	
	09/924,125	COMMUNI ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 26-45* is/are pending in the application.

4a) Of the above claim(s) *1-6,15-22 and 29-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14,23,24 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 18 on June 13, 2003 has been entered in full. Claims 7-9, 11-13, and 23 have been amended. Claims 1-24 and 26-45 are pending. Claims 7-14, 23, 24, and 26-28 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Amendment in Paper No. 8

The amendment in Paper No. 8 has not been entered because the amendment does not correspond to the specification. Specifically, (1) the first requested amendment appears to correspond to page 16, lines 25-26, not page 17, lines 6-7. Page 17 (lines 6-7) provides the description of Figure 4, whereas the replacement paragraph refers to Figure 1, which represents the nucleotide and amino acid sequences of the human GPR86 receptor; (2) the second requested amendment (the NF-kB binding element) appears to correspond to page 40, the second paragraph, not page 41, lines 4-18; (3) the third requested amendment (specific oligonucleotide primers) appears to correspond to page 56, last paragraph, not page 58, lines 16-26; and (4) the 4th requested amendment (RT-PCR experiments) appears to correspond to page 58, first paragraph, not page 58 or page 60.

III. Claim rejections under 35 U.S.C. § 101

The rejection of claims 7-14, 23, 24, and 26-28 under 35 U.S.C. § 101 remains. The basis for this rejection is set forth at pages 3-5 of the previous Office Action (Paper No. 14, December 17, 2002).

Applicants argue that the GPR86 receptor of the present invention is a receptor for ADP, a molecule which is well established in the art as regulating a number of cellular physiological functions, and as such has a specific, substantial, and credible utility. Accordingly, this utility is imputed onto GPR86 as a receptor for ADP. Applicants further submit that as discussed by telephone with the Examiners, Applicants' showing of an established utility for ADP establishes a corresponding utility for GPR86 as a receptor for ADP.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. As the Examiner pointed out during the telephone interview, Applicants are required to provide evidence to establish a well established utility for GPR86, not just for ADP. The biological functions or utility of ADP does not necessarily provide a well-established utility for GPR86 because ADP binds to receptors with different structures and biological functions (see, e.g., Abbracchio and Burnstock, Pharmac. Ther., 64:445, 1994) and it would require undue experimentation to determine the specific biological functions of GPR86, which is not allowed under 35 U.S.C. § 101.

Applicants argue that the present specification teachs that GPR86 is a member of the P2Y family of adenine nucleotide GPCR family and the P2Y receptor family of receptors has been shown to mediate a number of pharmacological and physiological response in multiple cell types. Applicants submit that GPR 86 receptor shares 48%

amino acid sequence homology with P2Y12 receptor, which corresponds to a platelet derived ADP receptor. Thus, GPR86 is a member of a receptor family which is known to mediate numerous physiological responses, and as such, has a specific, substantial, and credible utility.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the sequence homology of GPR86 with P2Y12 is low, one cannot assign the same biological functions to GPR86 merely based upon the low sequence homology. Secondly, while GPR86 may be considered as a member of the P2Y family of adenine nucleotide GPCR family, it does not render GPR86 a specific biological function and does not provide a well-established utility for GPR86 because the members of the family have different structure and biological functions and the biological function or physiological significance of each member needs to be determined specifically.

Applicants argue that GPR86 has a particular tissular distribution which is indicative of its role in physiological process. Applicants submit that the interaction of GPR86 with ADP can be used as the basis of assays for the diagnosis or monitoring of diseases, disorders, or processes involving GPR86 signaling.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while the particular tissue distribution might provide a clue on the biological functions or physiological significance of GPR86, it does not provide conclusive evidence on the specific biological functions or physiological significance of GPR86. Furthermore, diagnosis or monitoring of unspecified diseases or disorders does not constitute a specific and substantial utility for the present invention.

Applicants argue that GPCRs are well known to those of skill in the art as transmembrane proteins which function to transduce a signal from the outside to inside of a cell. Applicants further submit that the use of a protein's tissue or cellular distribution is widely accepted by those of skill in the art for the purpose of making deductions as to the physiological role of the protein, and its possible functions in a disease state.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, members of GPCRs do not have a common use; i.e., each member of the GPCR family has a distinct biological function, which needs to be determined individually. Secondly, while the tissue distribution pattern of a protein can be used as an approach in determining the biological functions of the protein, knowing the distribution patter is not equal to knowing the biological functions of the proteins. Since the biological functions or physiological significance of the protein is unknown, the present invention is not useful in its currently available form.

Applicants argue that the Examiner seems to be asserting that the only disclosure which would satisfy the utility requirement would be full chracterization of protein physiology, and a complete description of protein function. Applicants further argue that the specification teaches GPR86 is a GPCR, its natural ligand, ADP, its expression in lymphocytic cells, platelets, spleen cells, and the brain, imputing a role for GPR86 in diverse physiological process including immune processes, cancer, thrombosis, and neurotransmission. Applicants submit that given the teachings in the specification, one of skill in the art would readily appreciate and concur with the asserted usefulness of the present invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, Applicants mischaracterize the Examiner's position. The Examiner never states or implies that only a full characterization of protein physiology and a complete description of protein function would satisfy the utility requirement. In fact, as long as the present invention has a specific, substantial, and credible utility or a well-established utility, it would satisfy the utility requirement under 35 U.S.C. § 101. It is noted that the present invention is drawn to a method of screening for a candidate modulator of GPR86 activity or function. However, the specification fails to disclose the biological functions or physiological significance of the GPR86. Thus, the screening method does not have a patentable utility. Secondly, even though the specification discloses the natural ligand and the tissue distribution pattern of GPR86, the utility or usefulness of the screening method in its current available form is still unclear from the record. Therefore, rejection of the claims under 35 U.S.C. § 101 is required.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

The rejection of claims 7-14, 23, 24, and 26-28 under 35 U. S. C. § 112, 1st paragraph remains. The basis for this rejection is set forth at pages 3-5 of the previous Office Action (Paper No. 14, December 17, 2002).

The Applicants' argument about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set forth above.

V. Claim Rejections Under 35 U. S. C. § 112, 2nd Paragraph

The rejection of claims 7-14, 23, 24, and 26-28 under 35 U. S. C. § 112, 2nd paragraph remains. The basis for this rejection is set forth at page 6 of the previous Office Action (Paper No. 14, December 17, 2002).

Applicants argue that by the amendment of December 5, 2001, the amino acid sequence of GPR86 was indicated to be set forth in SEQ ID NO: 2. Applicants' argument has been fully considered, but is not deemed to be persuasive, because the term, "GPR86", is not unambiguously defined in the specification. The amendment to the specification (line 15 of page 2) states that "The present invention is related to the GPR86 (P2Y13) receptor (or any homologous sequence), the nucleic acid sequence of which is set forth in SEQ ID NO: 1 and the amino acid sequence of which is set forth in SEQ ID NO: 2 and .....". If "(or any homologous sequence)" were deleted, the definition in the specification would be unambiguous; however, the term "GPR86", as written now, may comprise a homologous sequence of GPR86, rendering the claims indefinite. If Applicants intend to claim GPR86 only, the term should be modified by the amino acid sequence of SEQ ID NO: 2 in each independent claim; if applicants intend to claim both GPR86 of SEQ ID NO: 2 and its homologues, they should clearly indicate so.

The amended claim 23 is indefinite also because measuring the binding of an agent to GPR86 does not necessarily identify an agent that modulates the function of GPR86, which is not disclosed in the specification.

VI. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a

possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
August 18, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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